DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
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January 28, 2003

WARNING LETTER

NWE-09-03W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Kenneth Byers, CEO
Media Power, Inc.
60 York Street
Portland, ME 04101

Dear Mr. Byers:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your distribution center, Media Power, Inc. located at 474 Riverside Industrial Parkway, Portland, ME 04103 on August 28, 2002. Labeling for your firm's products CalMax, Nu-Zymes and B1-Bomber was collected during the inspection and a review of that labeling indicates serious violations of the Federal Food, Drug and Cosmetic Act (the Act). You can find the Act along with the food, drug and dietary supplement labeling regulations on the Internet through links on FDA's web page www.fda.gov.

We have determined that your products CalMax, Nu-Zymes and B1-Bomber are drugs under Section 201(g)(1)(B) of the Act because they are intended to treat, mitigate, cure, or prevent disease.

Promotional material accompanying your products is labeling, as defined in Section 201(m) of the Act, and includes the Ultimate Health booklet and the MPDirect catalog. These materials include the following, and other, therapeutic claims:

1. **"Ultimate Health", Copyright 2001 Media Power, Inc.**

   CalMax sections of the booklet:

   - "What Results Can I Expect with CalMax?... . People suffering from

symptoms associated with chronic illnesses such as arthritis, fibromyalgia, low back pain, insomnia or fatigue, have reported noticeable results within the first 3-4 weeks of using CalMax consistently ... ."

- The booklet also suggests that CalMax is useful in treating or preventing migraines, anxiety, depression, chronic fatigue syndrome, hypertension, hypoglycemia, and obesity.

Nu-Zymes sections of the booklet:

- The booklet suggests that CalMax is useful in treating or preventing a variety of diseases, including arthritis, colon cancer, diabetes, hypertension, heart disease, and arteriosclerosis.

B1-Bomber sections of the booklet:

- "[M]any people report relief from ... headaches, migraines, joint pain, panic attacks, anxiety ... ."

- The booklet also suggests that B1-Bomber is useful in preventing or treating ADD (attention deficit disorder), arthritis, and heart disease.

Therapeutic claims regarding these products are also included in the "Testimonials From People Like You" sections of the Ultimate Health booklet, including the following:

- CalMax: "...I have severe arthritis. ...CalMax has helped me a lot." "I have had low back pain and hip pain continuously for over 3 years.... After 2 cans of the CalMax the pain has subsided...." "I took 2 doses and all my pain has disappeared."

- Nu-Zymes: "... miracle of miracles I no longer have any symptoms or attacks of acid reflux." "I've only been taking these [Nu-Zymes] 3-4 days and I am digesting my food much better. I've been fighting digestive problems (irritable bowel) for years...." "I find Nu-Zymes helps me as I suffer from severe digestive problems due to fibromyalgia. ...it makes quite a difference in my ability to digest food."

- B1-Bomber: "...no headaches or migraines (from which I have suffered since 1984)." "...has also helped my arthritis." "I was going through Chronic Fatigue and spent most of my afternoons resting in bed. I've been taking the B1-Bomber for about 3 months and have noticed a marked improvement in my fatigue."

2. **"MPDirect"**

- B1-Bomber: "Many people who use B1-Bomber report significant relief ... from symptoms such as headaches, ... panic attacks ... ."

These claims cause your CalMax, B1-Bomber and Nu-Zymes products to be drugs as defined in Section 201(g)(1)(B) of the Act. Because we are unaware of any evidence that these products are generally recognized as safe and effective when used as labeled, they are also new drugs as defined under Section 201(p) of the Act. Under Section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application.

These products are further misbranded under Section 502(f)(1) of the Act in that they fail to bear adequate directions for use.

Even if your products CalMax, B1-Bomber, and Nu-Zymes did not contain disease claims in their labeling that cause them to be drugs, they would still be misbranded as dietary supplements.

For example, as dietary supplements the CalMax, Kid's CalMax, Nu-Zymes, and B1-Bomber products are misbranded under section 403(q)(5)(F) of the Act because the format of the supplement facts panel for these products is not in compliance with 21 CFR 101.36. The B1-Bomber product is also misbranded under section 403(s)(2)(B) because it is not labeled in accordance with section 201(ff)(2)(C) of the Act in that the statement of identity does not include the term "dietary supplement" or other descriptive term authorized by 21 CFR 101.3(g).

In addition, the Nu-Zymes product is misbranded under section 403(a)(1) of the Act because the Ultimate Health booklet statement "Nu-Zymes is manufactured in an F.D.A. ... approved facility" is false and misleading because FDA does not approve facilities that manufacture dietary supplements.

This letter is not intended to be an all-inclusive list of the deficiencies in your products and their labeling. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations. You should review the labeling for all of your products to assure that it is in compliance. We may take further action if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating.

You should notify this office, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. Copies of the revised labeling should also be submitted. If corrective action cannot be completed within 15 working days, state the reason(s) for delay and the time at which the corrections will be completed.

You should direct your reply to Patricia Murphy, Compliance Officer at One Montvale Avenue, Suite 4, Stoneham, MA 02180. If you have any questions concerning this letter, please contact Ms. Murphy at 781-596-7758.

Sincerely,

Gail T. Costello
Director
New England District

cc: Mr. Christopher M. Homer, President
Media Power, Inc.
60 York Street
Portland, ME 04101